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Price: EUR 3

⁽¹⁾ Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 1170/2011

of 16 November 2011

refusing to authorise certain health claims made on foods and referring to the reduction of disease risk**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 17(3) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.
- (3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Prof. Dr. Moritz Hagenmeyer and Prof. Dr. Andreas Hahn, submitted

pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of water and reduction of the risk of development of dehydration and of concomitant decrease of performance (Question No EFSA-Q-2008-05014) ⁽²⁾. The claim proposed by the applicant was worded as follows: 'Regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance'.

- (6) Article 2(2)(6) of Regulation (EC) No 1924/2006 defines reduction of disease risk claims as 'any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease'. Upon request for clarification, the applicant proposed water loss in tissues or reduced water content in tissues as risk factors of dehydration. On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 16 February 2011 that the proposed risk factors are measures of water depletion and thus are measures of the disease. Accordingly, as a risk factor in the development of a disease is not shown to be reduced, the claim does not comply with the requirements of Regulation (EC) No 1924/2006 and it should not be authorised.
- (7) Following an application from FrieslandCampina, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of acidic calcium-containing fruit juices on reduction of tooth demineralisation (Question No EFSA-Q-2009-00501) ⁽³⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Reduced risk for dental erosion'.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ EFSA Journal 2011; 9(2):1982.

⁽³⁾ EFSA Journal 2011; 9(2):1983.

- (8) Article 2(2)(6) of Regulation (EC) No 1924/2006 defines reduction of disease risk claims as 'any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease'. Upon request for clarification, the applicant proposed tooth demineralisation as a risk factor for tooth erosion. On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 18 February 2011 that a cause and effect relationship had not been established between the consumption of acidic calcium-containing fruit juices in replacement of fruit juice without added calcium and the reduction of tooth demineralisation. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (9) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,
- HAS ADOPTED THIS REGULATION:
- Article 1*
- The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.
- Article 2*
- This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 November 2011.

For the Commission

The President

José Manuel BARROSO

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Water	Regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance	Q-2008-05014
Article 14(1)(a) health claim referring to a reduction of a disease risk	Calcium-containing fruit juices	Reduced risk for dental erosion	Q-2009-00501

COMMISSION REGULATION (EU) No 1171/2011

of 16 November 2011

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.
- (3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Yakult Europe BV, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of live *Lactobacillus casei* strain Shirota and maintenance of the upper respiratory tract defence against pathogens by maintaining immune defences (Question No EFSA-Q-2010-00137) ⁽²⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Daily consumption of live *Lactobacillus casei* strain Shirota as present in a

fermented milk product helps maintain the upper respiratory tract defences by helping to support immune functions'.

- (6) On 18 October 2010, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of *Lactobacillus casei* strain Shirota and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) Following an application from Piimandusühistu E-Piim (Dairy Cooperative E-Piim), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of *Lactobacillus plantarum* TENSIATM in the semi-hard Edam-type 'heart cheese' of HarmonyTM and maintenance of normal blood pressure (Question No EFSA-Q-2010-00950) ⁽³⁾. The claim proposed by the applicant was worded as follows: 'Regular consumption (at least three weeks) of 50 g/day Sūdamejuust ("heart cheese") of HarmonyTM brand comprising probiotic *Lactobacillus plantarum* TENSIATM helps to maintain the cardio-vascular system/heart health through reduction of blood pressure/symbol of heart'.
- (8) On 14 February 2011, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of *Lactobacillus plantarum* TENSIATM in the semi-hard Edam-type 'heart cheese' of HarmonyTM and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (9) The health claims subject to this Regulation are health claim as referred to in point (a) of Article 13(1) of Regulation (EC) No 1924/2006 and may benefit from the transitional period laid down in Article 28(5) of that Regulation. As the Authority concluded that cause and effect relationships have not been established between the foods and the claimed effects, the claims do not comply with Regulation (EC) No 1924/2006, and therefore they may not benefit from the transitional period provided for in that Article.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ The EFSA Journal 2010; 8(10):1860.

⁽³⁾ The EFSA Journal 2011; 9(2):1981.

- (10) In order to ensure that this Regulation is fully complied with, both food business operators and the national competent authorities should take the necessary actions to ensure that, at the latest 6 months following the entry into force of this Regulation, products bearing the health claims listed in its Annex are no longer present on the market.
- (11) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.
2. However, products bearing these health claims placed on the market or labelled prior to the date of entry into force of this Regulation may remain on the market for a maximum period of 6 months after that date.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 November 2011.

For the Commission

The President

José Manuel BARROSO

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Live <i>Lactobacillus casei</i> strain Shirota	Daily consumption of live <i>Lactobacillus casei</i> strain Shirota as present in a fermented milk product helps maintain the upper respiratory tract defences by helping to support immune functions	Q-2010-00137
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Lactobacillus plantarum</i> TENSIA™	Regular consumption (at least three weeks) of 50 g/day Sūdamejuust ('heart cheese') of Harmony™ brand comprising probiotic <i>Lactobacillus plantarum</i> TENSIA™ helps to maintain the cardio-vascular system/heart health through reduction of blood pressure/symbol of heart	Q-2010-00950

COMMISSION IMPLEMENTING REGULATION (EU) No 1172/2011**of 16 November 2011****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 17 November 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 November 2011.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	AL	58,9
	AR	40,4
	MA	48,6
	MK	64,0
	TR	87,5
	ZZ	59,9
0707 00 05	AL	73,2
	EG	161,4
	TR	124,2
	ZZ	119,6
0709 90 70	MA	61,2
	TR	146,1
	ZZ	103,7
0805 20 10	MA	91,2
	ZA	65,5
	ZZ	78,4
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	HR	82,7
	IL	73,3
	MA	79,7
	TR	77,4
	ZZ	78,3
0805 50 10	TR	53,2
	ZA	43,5
	ZZ	48,4
0806 10 10	BR	217,4
	CL	70,8
	LB	292,8
	PE	200,1
	TR	144,7
	US	254,9
	ZA	77,5
	ZZ	179,7
0808 10 80	CA	86,1
	NZ	136,4
	TR	95,1
	US	141,3
	ZA	142,3
0808 20 50	ZZ	120,2
	CL	73,3
	CN	97,5
	TR	85,0
	ZA	73,2
	ZZ	82,3

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION DECISION

of 11 November 2011

amending Decisions 2010/2/EU and 2011/278/EU as regards the sectors and subsectors which are deemed to be exposed to a significant risk of carbon leakage

(notified under document C(2011) 8017)

(Text with EEA relevance)

(2011/745/EU)

THE EUROPEAN COMMISSION,

paragraphs 14 to 17 of Article 10a of that Directive, following a change that has a substantial impact on the sector's or subsector's activities.

Having regard to the Treaty of the Functioning of the European Union,

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC⁽¹⁾, and in particular Article 10a(1) and (13) thereof,

Whereas:

- (1) Commission Decision 2010/2/EU⁽²⁾ determines, pursuant to Directive 2003/87/EC, a list of sectors and subsectors which are deemed to be exposed to a significant risk of carbon leakage.
- (2) Commission Decision 2011/278/EU⁽³⁾ determines transitional Union-wide rules for the harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC.
- (3) In accordance with the second subparagraph of Article 10a(13) of Directive 2003/87/EC, the Commission may, every year add a sector or subsector to the list of sectors and subsectors which are deemed to be exposed to a significant risk of carbon leakage. It has to be demonstrated, in an analytical report, that the sector or subsector satisfies the criteria set out in

- (4) In order to determine the sectors or subsectors deemed to be exposed to a significant risk of carbon leakage, the Commission has to assess, at Union level, the extent to which it is possible for the sector or subsector concerned, at the relevant level of disaggregation, to pass on the direct cost of the required allowances and the indirect costs from higher electricity prices resulting from the implementation of Directive 2003/87/EC into product prices without significant loss of market share to less carbon efficient installations outside the Union. Those assessments are to be based on an average carbon price according to the Commission's impact assessment accompanying the package of implementation measures for the Union's objectives on climate change and renewable energy for 2020 and, if available, trade, production and value added data from the three most recent years for each sector or subsector.
- (5) Some sectors and subsectors, such as the manufacture of bricks and roof tiles that had not been completely analysed due to time constraints and limited data quality and availability, were not added to the list published in the Annex to Decision 2010/2/EU.
- (6) The sector of 'Manufacture of bricks, tiles and constructions products, in baked clay' (NACE code 2640) has been reassessed in 2010. That qualitative assessment demonstrated challenging market characteristics, such as growing trade, in particular increasing trend in imports from low cost manufacturing countries, increased international competitive pressure, a significant share of production in the Union served by small and medium sized enterprises, and only modest profit margins for the years evaluated compared to the additional CO₂ cost, which limit the capacity of installations to invest and reduce emissions. Based on the combined impact of those factors, the sector should be deemed to be exposed to a significant risk of carbon leakage.

⁽¹⁾ OJ L 275, 25.10.2003, p. 32.

⁽²⁾ OJ L 1, 5.1.2010, p. 10.

⁽³⁾ OJ L 130, 17.5.2011, p. 1.

- (7) Furthermore, it has been demonstrated that the sector of 'Production of salt' (NACE code 1440) satisfies the quantitative criteria set out in Article 10a(14) to (17) of Directive 2003/87/EC following an identification of additional installations from the sector in the Community Independent Transaction Log (CITL) which was used as the main source to calculate the direct cost of the allowances. That sector should therefore be added to the list of sector or subsectors deemed to be exposed to a significant risk of carbon leakage. The identification of installations in the CITL as belonging to that sector has no impact on the status in terms of a significant risk of carbon leakage of other sectors and subsectors.
- (8) Some sectors not found to be exposed to a significant risk of carbon leakage at the NACE 4-level in Decision 2010/2/EU were disaggregated and a number of corresponding subsectors, for which certain specific distinguishing characteristics led to a significantly different impact from the rest of the sector, were assessed. Where this assessment leads to the conclusion that sectors or subsectors could be clearly distinguished from other sectors and subsectors on the basis of specific characteristics and satisfy the quantitative criteria set out in Article 10a(15) or (16) of Directive 2003/87/EC, they can be added to the list of products deemed to be exposed to a significant risk of carbon leakage. The sectors 'Cocoa paste (excluding containing added sugar or other sweetening matter)', 'Cocoa butter, fat and oil' and 'Cocoa powder, not containing added sugar or other sweetening matter' should therefore be added to the list.
- (9) The further analysis called for by the second paragraph of Article 1 of Decision 2010/2/EU having been conducted, that paragraph should be deleted. The Commission found no evidence of the necessary intensity of trade that would justify inclusion of the concerned sectors to the list of sectors and subsectors deemed to be exposed to a significant risk of carbon leakage.
- (10) Decisions 2010/2/EU and 2011/278/EU should therefore be amended accordingly.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Climate Change Committee,

HAS ADOPTED THIS DECISION:

Article 1

Amendments to Decision 2010/2/EU

Decision 2010/2/EU is amended as follows:

- (1) in Article 1, the second paragraph is deleted;
- (2) the Annex to Decision 2010/2/EU is amended in accordance with Annex I to this Decision.

Article 2

Amendments to Annex I to Decision 2011/278/EU

Annex I to Decision 2011/278/EU is amended in accordance with Annex II to this Decision.

Article 3

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 11 November 2011.

For the Commission

Connie HEDEGAARD

Member of the Commission

ANNEX I

The Annex to Decision 2010/2/EU is amended as follows:

(1) in Section 1.2, the following entry is inserted in the table:

NACE code	Description
'1440	Production of salt'

(2) paragraph Section 2 is amended as follows:

(a) the heading is replaced by the following:

'BEYOND NACE-4 LEVEL BASED ON THE QUANTITATIVE CRITERIA SET OUT IN PARAGRAPH 15 OR 16 OF ARTICLE 10a OF DIRECTIVE 2003/87/EC';

(b) the following entries are inserted after the entry 155154:

Prodcom code	Description
'15841100	Cocoa paste (excluding containing added sugar or other sweetening matter)
15841200	Cocoa butter, fat and oil
15841300	Cocoa powder, not containing added sugar or other sweetening matter'

(3) in Section 3, the following entry is inserted after the entry 2416:

NACE code	Description
'2640	Manufacture of bricks, tiles and constructions products, in baked clay'

ANNEX II

In Annex I to Decision 2011/278/EU, the entries corresponding to product benchmarks 'Facing bricks', 'Pavers' and 'Roof tiles' are replaced by the following:

Product benchmark	Definition of products covered	Definition of processes and emissions covered (system boundaries)	Carbon leakage exposure as determined by Decision 2010/2/EU for the years 2013 and 2014	Benchmark value (allowances/t)
'Facing bricks	Facing bricks with a density > 1 000 kg/m ³ used for masonry based on EN 771-1, excluding pavers, clinker bricks and blue braised facing bricks.	All processes directly or indirectly linked to the production processes raw material preparation, component mixing, forming and shaping of ware, drying of ware, firing of ware, product finishing and flue gas cleaning are included.	yes	0,139
Pavers	Clay bricks used for flooring according to EN 1344.	All processes directly or indirectly linked to the production processes raw material preparation, component mixing, forming and shaping of ware, drying of ware, firing of ware, product finishing and flue gas cleaning are included.	yes	0,192
Roof tiles	Clay roofing tiles as defined in EN 1304:2005 excluding blue braised roof tiles and accessories.	All processes directly or indirectly linked to the production processes raw material preparation, component mixing, forming and shaping of ware, drying of ware, firing of ware, product finishing and flue gas cleaning are included.	yes	0,144'

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